

08/087,132 07/02/93



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APPLICATION NUMBER 08/087,132	FILING DATE 07/02/93	FIRST NAMED APPLICANT GENEZYME CORPORATION, LEGAL DEPARTMENT NO. 1 MOUNTAIN ROAD FRAMINGHAM MA 01701	ATTORNEY DOCKET NO. CARLSON, K
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186 EXAMINER

ART UNIT	PAPER NUMBER 02/21/97 45
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DATE MAILED:

Note That There are TWO PERIODS for Response to this Office Act

This is a communication from the examiner in charge of your application.
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OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 1-17-97 (#43)

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 months and 21 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a) for the 3 month SSP only.

Disposition of Claims

☒ Claim(s) 226, 227 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 226, 227 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Serial Number 08/087132
Art Unit 1801

Claims 1-225 have been cancelled. Claims 226 and 227 are currently under examination.

**NOTE THAT THERE ARE TWO PERIODS
FOR RESPONSE IN THIS OFFICE ACTION**

Suspension of prosecution as set forth in Paper #43 mailed October 28, 1996, is removed.

New Rejections

Claims 226 and 227 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA encoding CFTR, this DNA having silent point mutations in bases 908 to 936, this DNA having a non-coding intervening sequence downstream of base 907 (the cryptic promoter), and this DNA being placed in a low copy plasmid, in an E. coli host. The specification does not reasonably provide enablement for all DNAs encoding CFTR that is capable of stable propagation in E. coli. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims for all of the reasons set forth in Papers #2 (mailed 6/22/92), #5, (mailed 3/12/93), #12 (mailed 6/16/94), #16 (mailed 6/16/94), #25 (mailed 12/9/94), and #34 (mailed 12/22/95). Applicants are additionally referred to the telephonic interview held 1/31/96, Paper #35.

Claim 226 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 226 refers to a table and tables cannot be incorporated into a claim.

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Art Unit 1801

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **A shortened statutory period for response to this action is set to expire THREE MONTHS from the date of this action.** The shortened statutory period can be extended, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of this Office action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this Office action.

Applicants should note that this is the first period for response alluded to at the beginning of the Office Action. It is a regular shortened statutory period extendable under 37 CFR 1.136(a).

The following allowable claims are suggested for the purpose of an interference:

A purified and isolated DNA molecule that encodes human cystic fibrosis transmembrane conductance regulator (CFTR) protein, said DNA molecule differing from the wild-type DNA molecule encoding CFTR by the presence of the point mutation T936C.

A purified and isolated DNA molecule that encodes human cystic fibrosis transmembrane conductance regulator (CFTR) protein, said DNA molecule differing from the wild-type DNA molecule encoding human CFTR by the presence of a non-coding intervening sequence placed downstream of nucleotide position 907 which disrupts the translocational reading frame of the encoding DNA.

A plasmid comprising a DNA molecule that encodes human cystic fibrosis transmembrane conductance regulator (CFTR) protein, said plasmid capable of propagating the DNA encoding human CFTR at low copy number of 25 copies or less in E. coli.

The suggested claim must be copied exactly, although other claims may be proposed under 37 CFR 1.605(a).

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Applicant should make the suggested claim within ONE MONTH or THIRTY DAYS from the date of this letter, whichever is longer. Failure to do so will be considered a disclaimer of the subject matter of this claim under the provisions of 37 CFR 1.605(a). THE PROVISIONS OF 37 CFR 1.136(a) DO NOT APPLY TO THIS TIME PERIOD.

Applicants should note that this is the second period for response alluded to at the beginning of this Office Action. This is a 30 day or 1 month time limit which is not extendable under 37 CFR 1.136(a) or (b).

Claims 225 and 226 are considered unpatentable over this suggested claim.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is (703) 308-0034. The Examiner can normally be reached daily except alternate Fridays from 7:30 A.M. to 5:00 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Vasu Jaganathan, can be reached at (703) 306-2777. The fax phone number for Group 1800, Art Unit 1801 is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group 1800 receptionist whose telephone number is (703) 308-0196.

See 2/13/97

RICHARD A. SCHWARTZ
SUPERVISORY PATENT EXAMINER
ART UNIT 1801
Group 1800


ROBERT A. WAX
SUPERVISORY PATENT EXAMINER
GROUP 180